UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,375	12/22/2000	Scott R. Presnell	99-106	2186

7590 11/18/2002

Jennifer K. Johnson, J.D.
ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102

EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/18/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/746,375	PRESNELL ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-20,22 and 24-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21, 23 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-28 are pending in the instant application.

Election/Restrictions

2. Applicant's election of Group V, Claims 21, 23 and 28, in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-20, 22 and 24-27 are withdrawn as being drawn to a non-elected invention.

Claims 21, 23 and 28 are currently under examination.

Priority

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). On the third line of the first sentence of the specification, 60/###,### should be replaced with 60/250,841.

Specification

4. The disclosure is objected to because of the following informalities: on page 16, line 27, page 17, line 4, +0and page 104, line 16, "#######" should be replace with a PCT application number.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 21, 23 and 28 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

Claims 21, 23 and 28 are directed to methods for detecting a genetic abnormality, cancer and inflammation in a patient, respectively, comprising hybridizing a polynucleotide comprising at least 14 contiguous nucleotides of SEQ ID NO: 1 with a genetic, tissue or biological sample from the patient, and comparing either the reaction product or the degree of hybridization with that of a control from a wild type patient, wherein a difference in the reaction product or degree of hybridization indicates a genetic abnormality, cancer or inflammation. However, the claimed methods do not have any specific and substantial utility, or a well established utility, as determined according to the current Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

The instant specification teaches that the nucleic acid molecule of SEQ ID NO: 1 encodes a protein designated ZCYTO18, which is presumably a cytokine based on cellular expression and structure (four-helical-bundle structure). The specification further teaches that ZCYTO18 was isolated from tissue known to have important immunological function and which contain cells which play a role in the immune system, (is expressed in CD3+ selected, activated periperal blood cells), that this suggests that ZCYTO18 expression may be regulated and increase after T cell activation, and may have an effect on the growth/expansion and/or differentiated state of T- or B-cells, T- or B-cell progenitors, NK cells or NK progenitors. On pages 67-68, and 101-102, the specification discloses that mice injected with ZCYTO18 adenovirus display weight-loss, loss of mobility and a failure to groom, and a reduction in circulating lymphocytes, which are changes typical of those seen during septic shock and other inflammatory conditions. Page 77 of the specification teaches that ZCYTO18 is located at the 12q15 region of chromosome 12, near 12q14, where another T-cell expressed cytokine, interferon-gamma, maps, and that several genes map to the ZCYTO18 locus that are associated with human disease states, such as cancer. The 12q13-q15 region is involved in a variety of malignant and benign solid tumors, with 12q15 as a common break point. Because there is evidence for cancer resulting from mutations in the 12q15 region, the specification asserts that ZCYTO18 may be directly involved in or associated cancers. Page 78 of the specification also teaches other diseases and genetic abnormalities associated with this chromosomal region, and data on pages 103-104 indicate that ZCYTO18 may have an inhibitory activity on the proliferation/and or growth of a promyelocytic tumor cell line. Based on these factors, the instant application asserts that nucleic acids encoding ZCYTO18 can be used in methods to diagnose a genetic abnormality, cancer or inflammation. However,

ZCYTO18 has not been shown to be involved in any genetic abnormality, cancer or inflammation. There are no genetic mutations in ZCYTO18 taught that would correlate with any genetic abnormality leading to any disease state or disorder, and there is no information presented in the instant specification that an increase or decrease in expression of ZCYTO18 is correlated with any type of cancer or inflammation. There is no nexus between any genetic abnormality, cancer or inflammation and the molecules of the instant invention, so that these methods do not have a specific and substantial utility. A stated belief that a correlation exists between the nucleic acids and the above diseases or disorders, based on the limited information in the specification, is not sufficient guidance to use the claimed polynucleotides in the methods of detection; it merely defines a starting point for further research and experimentation. There is no RFLP polymorphism disclosed for this gene, or any other type of alteration that would result in a change in structure or expression, so the use of the ZCYTO18 nucleic acids as a diagnostic or prognostic marker is conjectural and would not, on the basis of the disclosure, be considered useful by one of skill in the art.

The instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a specific or substantial utility. The proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed nucleic acids. This further characterization, however, is part of the act of invention and until it has been undertaken the Applicant's claimed invention is incomplete. Because there is no specific and substantial utility asserted, credibility cannot be assessed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 21, 23 and 28 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The effective priority date of claim 28 is accorded the filing date of this application, Dec. 22, 2000, because claimed invention was not described in the priority applications, Serial Numbers 60/172,105 and 60/250,841. The effective priority date of claims 21 and 23 is that of the provisional application, 60/172,105, Dec. 23, 1999, because the claimed inventions were described in that application.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Parham et al., WO 00/73457 A1, Dec. 7, 2000.

Claim 28 encompasses a method for detecting inflammation in a patient comprising incubating a polynucleotide comprising at least 14 contiguous nucleotides of SEQ ID NO: 1 with a tissue or biological sample from the patient and also with a control tissue or biological sample, and determining if there is an increase in hybridization in the patient relative to the control.

Parham et al. disclose a nucleic acid molecule (SEQ ID NO: 1) that is identified as a primate IL-D110 nucleic acid sequence, which is 99.7% identical to nucleotides 1-1087 of SEQ ID NO: 1 of the instant application. Parham et al. also teach on page 37, lines 31-36:

> "Another diagnostic aspect of this invention involves use of oligonucleotide or polynucleotide sequences taken from the sequence of an IL-D10. These sequences can be used as probes for detecting levels of the IL-D-10 message in samples from patients suspected of having an abnormal condition, e.g., inflammatory or autoimmune."

Therefore, Parham et al. describes the use of the nucleic acid molecule of SEQ ID NO: 1 or fragments thereof to diagnose inflammation, and meets the limitations of the claims. Applicants should note that under 35 U.S.C. 102, the invention in the prior art document need only have been described in order to meet the requirement.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600